



Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents in connection with patent application GB0323511.6 filed on 8 October 2003.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

Dated 14 July 2009

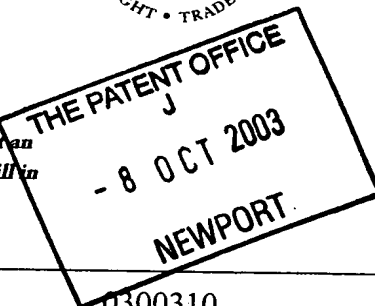
Patent Act 1977
(Rule 16)



08OCT03 E842948-1 C26047
P01/7700 0.00-0323511.6

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)



The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference

0300310

2. Patent application number

(The Patent Office will fill in this part)

0323511.6

3. Full name, address and postcode of the or of each applicant (underline all surnames)

SMITHS GROUP PLC
765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number (if you know it)

8032310001 ✓

If the applicant is a corporate body, give the country/state of its incorporation

GB

4. Title of the invention

VALVES AND SUCTION CATHETER
ASSEMBLIES

5. Name of your agent (if you have one)

J. M. FLINT

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number (if you know it)

1063304001 ✓

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

YES

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body.
- See note (d))

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form.
Do not count copies of the same document

Continuation sheets of this form

Description 9

Claim(s)

Abstract

Drawing(s) 2 x 2

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11. I/We request the grant of a patent on the basis of this application.

Signature

Date 07/10/03

12. Name and daytime telephone number of person to contact in the United Kingdom

J. M. FLINT 020 8457 8220

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- Once you have filled in the form you must remember to sign and date it.
- For details of the fee and ways to pay please contact the Patent Office.

VALVES AND SUCTION CATHETER ASSEMBLIES

This invention relates to valves and suction catheter assemblies.

Closed system suction catheter assemblies are used to remove secretions from within a tracheal tube or the respiratory passages of a patient. The assembly comprises a manifold at one end with a sliding seal through which a suction catheter can be advanced and withdrawn. A flexible envelope is joined at one end to the manifold and encloses the catheter along its length. The other end of the envelope and the catheter are joined with a rear end component including a suction control valve and a connector. The connector connects the catheter to a suction source and the valve enables the clinician to control the suction applied by the catheter.

Suction catheter assemblies are disposable, single-patient items so it is important that their cost is low. The cost of the valve contributes a significant part to the overall cost of the assembly so it is important that this can be made at low cost whilst also operating efficiently with low risk of blockage and leakage. Various forms of suction control valves have been described previously such as in US 5269728, US 5300043, US 4569344, US 4638539, US 4836199, US 4872579, US 5277177 and US 5215522. There are also applications other than closed system suction catheters where similar forms of valves are required.

It is an object of the present invention to provide an alternative valve and a suction catheter assembly including such a valve.

According to one aspect of the present invention there is provided a valve for controlling flow of fluid between a first passage and a second passage, the valve including a valve member that is slidable relative to a housing between a first position in which flow between the first and second passages is enabled and a second position in which flow is prevented, the valve including a locking member rotatably mounted with the housing and displaceable between a first position in which it allows movement of the valve member and a second position in which it prevents displacement of the valve member from the second position.

The valve preferably includes resilient means urging the valve member to the second position. One end of the resilient means may engage a surface of the locking member, which is preferably in the form of an end cap.

According to another aspect of the present invention there is provided a suction catheter assembly including a suction catheter and a valve according to the above one aspect of the invention connected at a machine end of the catheter.

A closed system suction catheter assembly including a suction control valve, according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a side elevation view of the assembly;

Figure 2 is a perspective view of the valve from the rear end, to one side and above when unlocked;

Figure 3 is a sectional elevation view of the valve in an open state; and

Figure 4 is a perspective view of the valve when closed and locked.

With reference first to Figure 1, the assembly includes a forward or patient end manifold coupling 1 having a first port 10 adapted to connect to a standard 15mm tracheal connector of the kind fitted to the machine end of a tracheal tube. At the opposite end of the coupling 1, and aligned with the first port 10, is a second port 11 containing a wiping seal 12 through which the suction catheter 20 can be extended and withdrawn. The coupling 1 has two further ports 13 and 14 aligned with one another and extending at right angles to the first and second ports 10 and 11. These further ports 13 and 14 are connected to two limbs of a patient ventilation system (not shown). The ports may have swivels. Alternative forms of coupling are possible, such as with only one further port.

The suction catheter 20 is flexible, typically being about 500mm long and having an external diameter of about 5mm. The rear, machine end 21 of the catheter 20 is connected to a suction control valve 30 and its forward end 22 locates just forwardly of the seal 12 in the patient end coupling 1. A flexible envelope 23 extends around the catheter 20, its forward end being joined to the coupling 1 and its rear end being joined to the housing of the suction control valve 30. The flexible nature of the envelope 23 enables the catheter 20 to be pushed forwardly or pulled rearwardly through the seal 12 by manipulation through the envelope.

The length of the envelope 23 is chosen to prevent the forward end 22 of the catheter 20 being pulled through the seal 12. The suction control valve 30 connects via tubing 2 to a suction source 3. As so far described, the assembly is conventional.

With reference now also to Figures 2 to 4, the suction control valve 30 differs from previous valves in that it is operated by a slider 50 and can be locked in a closed position by a rotatable cap 70 at the end of the valve.

The valve 30 has an outer housing 31 of a rigid, transparent plastics material, such as polycarbonate, having a main body portion 32 extending axially of the catheter 20 and an outlet connection arm 33 inclined downwardly at an angle of about 30° . The angle of the outlet connection arm 33 is chosen to enable the valve 30 to be held comfortably in the hand, with the fingers under the arm and the thumb on top of the main body portion 32. The lower, free end of the arm 33 is tapered and stepped so that the suction tubing 2 can be pushed onto the arm and retained securely in position.

The rear end 21 of the suction catheter 20 is bonded into a short, tapered bore 34 located concentrically within an outer collar 35 at the forward end of the body portion 32. The rear end of the envelope 23 is secured between the outside of the collar 35 and an outer ring (not shown) fitted over the collar. The bore 34 communicates with a fluid passageway 36 through the valve 30 provided by a first passage or bore 37 extending axially within the main body portion 32 and a second passage or bore 38 extending through the outlet connection arm 33 and opening into the first bore through an aperture 4. The bore 37 has an internal annular

step 39 located just forwardly of the aperture 4. The step 39 has a tapering, sealing surface 40 on its rear-facing side.

The rear part of the bore 37 beyond the step 39 is divided into three sections 41, 42 and 43 separated from one another by two shallow internal steps 44 and 45 (Figure 3). The rear section 43, beyond the step 45, opens via a slot 46 into a channel 47 extending forwardly axially along the upper surface of the main body portion 32. The channel 47 extends between two side walls 48 and 49, which extend longitudinally of the housing 31 and have a curved upper edge highest midway along their length. The walls 48 and 49 project outwardly at an angle of about 45° to the vertical so that they are oriented at about 90° to one another.

The housing 31 contains a user-actuable valve member in the form of the slider 50, which is moulded of a hard, coloured plastics material, and which may be coded for different sizes. The valve member 50 has an internal, sealing portion 51 provided by a rod-shape piston 52 with an enlarged end 53 and supporting a cylindrical sleeve 54 of a soft, resilient elastomeric material. The rear end of the sleeve 54 abuts a flange 55 on the piston 52 and itself has an outwardly-projecting sealing flange 56 with a rounded edge. The diameter of the flange 56 is chosen so that it makes a sliding, wiping seal with the intermediate section 42 of the rear part of the bore 37. The sleeve 54 has a constant diameter forwardly of the flange 55. The forward end 57 of the sleeve 54 is closed and has a conical shape.

The piston 52 has an enlarged, barrel-shape rear end portion 59 with a cylindrical recess 60 extending axially and opening at its rear. A short beam 61 projects upwardly from the rear portion 59 through the slot 46 to the underside of an integral, cantilevered slider plate

62. The slider plate 62 is wider than the piston 52 and has a laterally-extending thumb bar 63 projecting from its upper surface about two-thirds the way along its length towards the forward end of the slider. The slider plate 62 extends forwardly along the channel 47 in the upper surface of the housing 31 so that the thumb bar 63 is accessible to the user. The top of the thumb bar 63 lies slightly below the upper edge of the walls 48 and 49 so that it is protected by the walls.

The housing 31 also contains a resilient member in the form of a helical, stainless steel spring 64, although other springs of a non-ferrous material, such as a hard plastics material, for example, polycarbonate, could be used. The spring 64 aligns axially of the bore 37 and is located between the rear, right-hand end of the valve member 50 and the inside of the housing 31. More particularly, the forward, left-hand end of the spring 64 locates in the recess 60 in the valve member 50 and its rear, right-hand end extends around a peg 65, which projects axially from the rear end cap 70.

The cap 70 has a generally cylindrical shape with a closed, rounded rear end 71 and an open forward end 72. The cap 70 is retained on the rear end of the housing 31 by an interengaging projection 73 and recess 74 on the outside of the housing and on the inside of the cap. The projection 73 and recess 74 are shaped to allow the cap 70 to be rotated about the axis of the bore 37 through an angle of about 40°. On its external surface the cap 70 has several longitudinally-extending shallow ribs 75 to improve grip (Figure 2). The cap 70 also has two larger fins 76 of triangular shape that form a continuation of the walls 48 and 49 when the cap is rotated into alignment, in an unlocked position. The external surface of the cap 70 between the two fins 76 is shaped to enable the rear end 66 of the slider plate 62 to

move rearwardly between the fins when the cap is in the unlocked position with the fins aligned with the walls 48 and 49, as shown in Figure 2. If, however, the cap 70 is rotated through 40° , as shown in Figure 4, one of the fins 76 will be moved to lie between the walls 48 and 49 in the path of the slider plate 62 and will prevent the plate being moved rearwardly. This effectively locks the valve 30 in its closed position. The cap 70 remains in its locked position by friction, a detent or the like until the user needs to unlock the valve.

The natural position of the valve 30 is where the spring 64 urges the valve member 50 forwardly to its full extent. In this position, the forward, conical end 57 of the sealing sleeve 54 is held against the tapered surface 40 on the step 39 to form a fluid seal. Because this seal is located between the bores 37 and 38, forwardly of the aperture 4, there can be no flow of material through the valve 30. The seal formed by the flange 56 at the rear end of the sleeve 54 with the intermediate section 42 of the rear part of the bore 37 provides an additional, dynamic, wiping seal with the intermediate section 42 of the rear part of the bore 37 to prevent escape of material from the valve; it also prevents passage of air to the suction bore 38 from the interior of the housing 31. When the cap 70 is turned to a locked position, one of the fins 76 is a slight interference fit across the rear end of the slider 62, thereby pushing it slightly forwards and improving the seal between the forward end 57 of the sleeve 54 and the sealing surface 40.

To open the valve 30 and allow suctioning, the user ensures the valve is in an unlocked state, grips the thumb bar 63 with his thumb and slides the slider 50 rearwardly to its full extent against the action of the spring 64 to the position shown in Figure 3. In this position the forward end 57 of the sealing portion 51 is held to the rear of the aperture 4 so

that material can flow from the main bore 37 to the suction bore 38. Suction applied by the suction source 3 to the suction bore 38 is communicated to the main bore 37 via the aperture 4 and, therefore, to the bore of the suction catheter 20 so that secretions or the like can be removed when the tip 22 of the catheter is advanced into the tracheal tube.

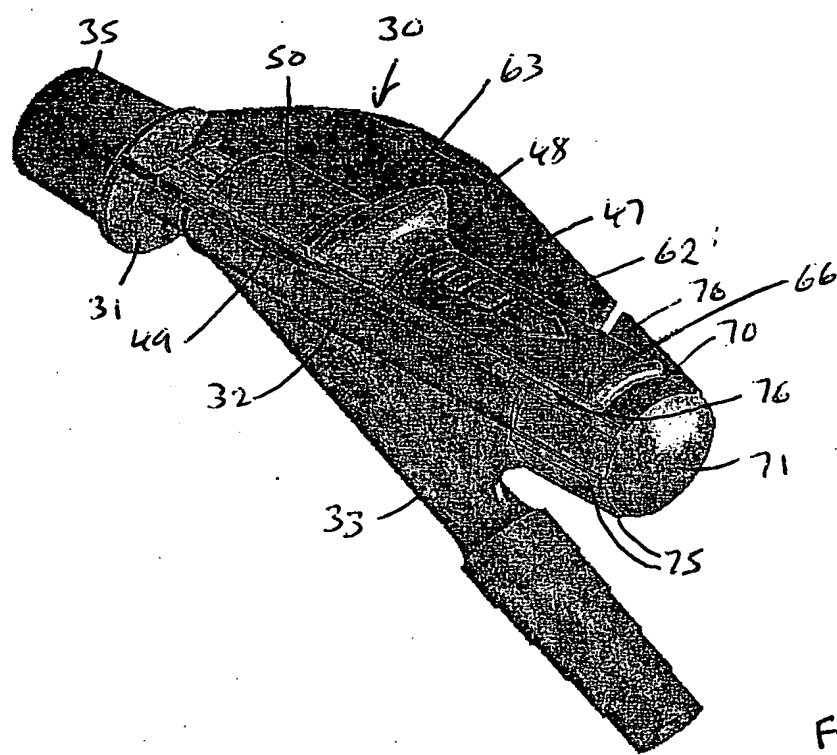
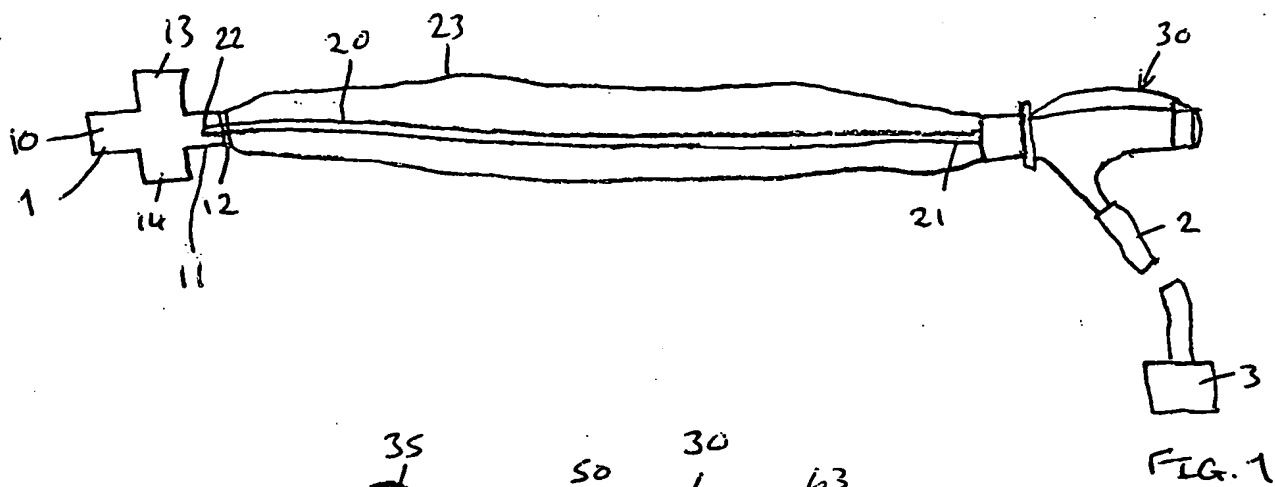
When released, the spring 64 returns the valve member 50 to its natural, forward, closed or sealing position.

When the valve 30 is open there is no impediment to flow between the two bores 37 and 38, compared with some previous valves where there is a risk that the valve member might cause solid materials carried in the fluid to block the valve. The open flow path makes it easier to clean, thereby enabling the assembly to be used for longer periods with low risk of infection. Even when the valve is unlocked, the sliding action needed to open it minimizes the risk of inadvertent actuation compared with some previous valves actuated by a press-down action. The two side walls effectively protect the slider from inadvertent contact. The axial sliding motion needed to operate the valve encourages the user to pull back the catheter in a straighter fashion when withdrawing from the tracheal tube. This reduces the risk that the catheter will be kinked. The locking arrangement enables the user to lock the valve closed when desired. Its construction also makes it readily apparent how the lock can be released when this is needed. The construction of the valve enables it to be gas sterilized in its natural, closed state because gas can penetrate all parts of the valve through its bores and the slot. The transparent housing enables the user to confirm the absence of blockages within the valve. Its simple construction enables the valve to be produced at low cost and with a low weight, thereby minimizing forces applied to the tracheal tube. The valve can be used with

single lumen catheters, as described, or with double lumen catheters where the additional lumen is for supply of an irrigating fluid.

The valve is not limited to use with suction catheters but could be used in other applications for controlling flow of fluid.

[Y:\PATENTS\SPEC\03\SSVL.doc]



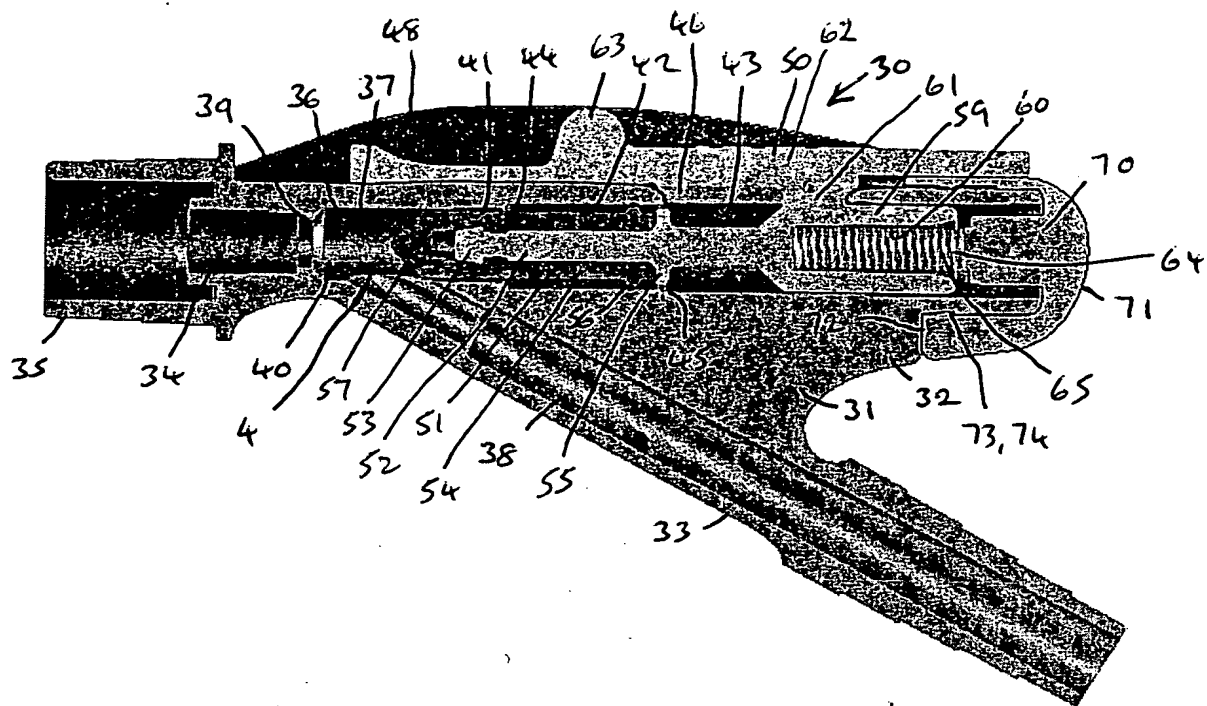


FIG. 3

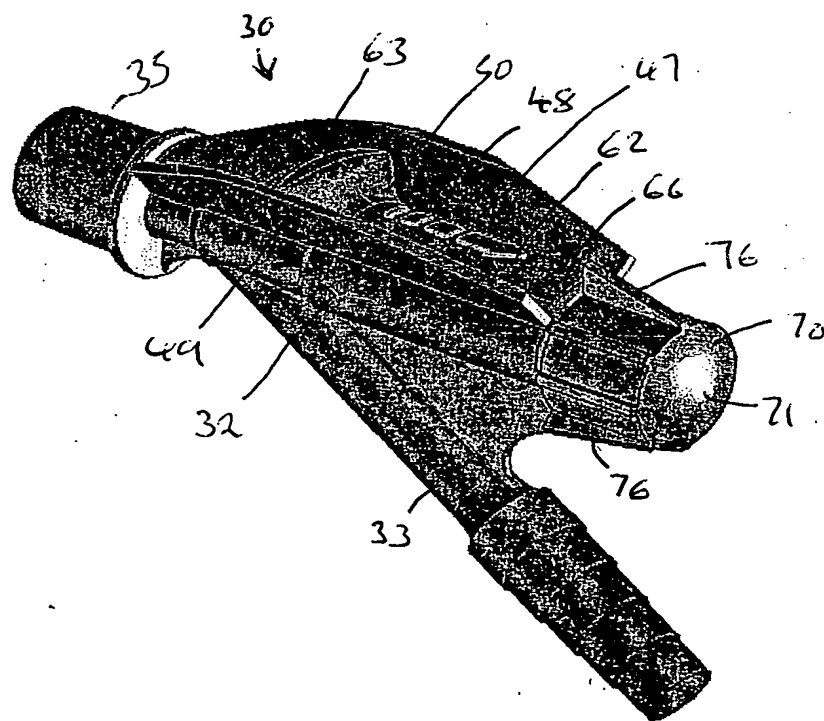


FIG. 4